August 16, 1999

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Dockets Management Branch (HFA-306)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 99N-1737
Request for Comments
Public Availability of Information on Clinical Trials

To whom it may concern:

I am respectfully submitting comments regarding the public health need for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act (PHS Act) and the impact of such an inclusion on device innovation and research in the United States. The importance of this issue must be underscored given the discrete possibility that such a data bank could directly conflict with the agency's statutory mission to "encourage" the development of useful devices in the U.S.

Before offering specific comments, I want to urge the Food and Drug Administration (FDA) to request a 2 year extension of time to prepare the report to Congress that is required under the FDA Modernization Act of 1997 (FDAMA). It is simply irresponsible for FDA to attempt to prepare this report without offering all interested parties ample opportunity to provide input. It appears that the FDA has totally neglected its responsibility to seek input for the first 19 months since the passage of FDAMA. Yet, the FDA insists that a 60-day comment period following the publication of an obscure notice in the Federal Register (FR) is adequate to gather information required for the task. Even the agency's attempt to convene a public meeting appears disingenuous. Although I have not been successful in getting transcripts of the meeting, I suspect that a 2-week notice announced in the FR went largely unnoticed by the parties with an interest in the issue and the eventual outcome.

I will not offer comments regarding the "feasibility" of including information on device investigations in a public data bank. My interpretation of section 113(b) of FDAMA places this responsibility with the FDA. I must admit that I find it quite surprising that FDA is soliciting public input on this issue as stated in the "Summary" section of the FR notice. I cannot imagine any non-governmental entities offering input of value in this area. It occurs to me that the FDA would, however, be in a much better position to assess the feasibility of incorporating device investigations if the agency had fulfilled its obligation to establish the data bank for drugs under Section 113(a).

For your consideration, I offer the following comments:

(I) **Public Health Need**

Comment 1: There is little information readily available to determine whether there is a true public health need to disclose information regarding device trials in a Department of Health and Human Services (DHHS) data bank.

Without information upon which a conclusion can be based, one can only offer an opinion. In order to determine whether a true need exists, one would have to be able to identify probable public health benefit that would likely be realized by patients having access to such information. Given that there are very few investigational devices used in the diagnosis or treatment of serious or life threatening conditions where no alternatives

99N-1737 C1

exist, any espoused need for greater access to device trial information is likely not genuine.

The FDA must resist the temptation to conclude that the existence of complaints by a few sponsors of device trials regarding the difficulty of enrolling patients is evidence of public health need. In most instances, the desire to expand the scope of device trials is simply related to a sponsor's desire to increase their rate of patient enrollment, to secure additional revenue and to build an expanded customer base, i.e., prescribing physicians.

Comment 2: It is impossible to generate the information necessary to determine whether there is a public health need to include device trials in the data bank without being given a definition of "serious and life-threatening conditions".

The inclusion of the discussion regarding treatment IDEs in the FR suggests that only the FDA is capable of recognizing a serious disease or condition when one exists. In the case of treatment IDEs, the FDA has admitted that it avoided defining "serious disease or condition" to preserve its discretion to determine which device trials are eligible. Unless the FDA provides insight into what criteria it uses to determine what conditions are serious, no meaningful assessment of public health need can be provided.

Comment 3: Any effort by the agency to restrict the definition of "serious and life-threatening conditions" only serves to diminish any benefits realized by the agency's eventual efforts to establish the data bank.

Should the FDA choose to use its current definition of "immediately life-threatening" diseases to identify the "serious and life-threatening conditions" for purposes of section 113(b), the public health need for any data bank will be severely minimized. Although I am not aware of the numbers of "treatment IDEs" in existence for devices, I suspect that they are extremely few. If the numbers are as low as I suspect, FDA need only look in its own administrative records to observe the rather scanty public health need for disclosure.

Comment 4: The concept of public health need suggests that there is a segment of the American population that is disadvantaged by not knowing of the existence of certain device trials. Knowledge of the existence of device trials is likely a minor determinant of enrollment eligibility and an individual's ability to participate in any given trial.

It is universally recognized that a patient's socioeconomic status is the major determinant of whether they can participate in a device trial, assuming they meet the eligibility criteria for enrollment. Information dissemination will negligibly contribute to satisfying any public health need. If a true public health need exists, DHHS would be better off rerouting the funds and resources needed to create and maintain the data bank to a program providing financial assistance to those patients unable to participate in a device trial.

(II) Impact of Device Innovation and Research in the United States

Comment 5: The FDA suggests that there may be an option for "voluntary disclosure" rather than a system of "mandatory disclosure". Any system based on voluntary disclosure will not insure that patients receive complete information upon which they can base decisions. Any system that does not require sponsors of studies to disclose information on their studies will not satisfy any public health need should one be determined to exist

Comment 6: The FDA indicates that information regarding device trials is "generally protected from public disclosure under FDA regulations". While this is correct, it is more

appropriate for the FDA to consider the protection from disclosure afforded to sponsors of device trials under the Federal Food, Drug, and Cosmetic Act (the Act).

Perhaps a review of the legislative history of the Act may provide insight into why Congress believed that it was important for the FDA to respect the privacy of developers of innovative devices while they are pursuing their developmental activities. Since sponsors of device trials are likely small entrepreneurial start-up companies, individual physician-investigators, or privately held corporations, it is best to allow them to approach device development without the pressures that disclosure of their activities in a DHHS data bank will create.

Comment 7: Disclosure of information on device trials in a DHHS data bank will place considerable pressure on sponsors, investigators, institutional review boards (IRBs) and the FDA to prematurely, or unnecessarily, expand the scope of studies.

Consumers who believe that they are appropriate candidates for a given study will put pressure on investigators and sponsors to include them in the trial. Desperate and demanding consumers are likely to insist that (1) they be included, even if they do not meet eligibility criteria, (2) they be given the device and not the control, thereby jeopardizing the study design, and (3) they receive follow-up from their own physician and not the investigator. Hospitals will be pressured to accept patients from outside their geographic areas and IRBs will inherit much of the responsibility for monitoring and judging the issues that increased consumer demand will create. Given that the Health Care Finance Administration authorizes reimbursement for many investigational devices, it is likely that this increased patient pressure will also impact our nation's health care cost-containment activities.

Comment 8: FDA and the device industry should consider how the systematic disclosure of the existence of a device trial would affect the disclosure of more detailed information within an IDE under the Freedom of Information Act.

Patients interested in participating in device studies are likely to request information regarding the regulatory history and the progress of the trial before pursuing enrollment. This has major cost implications for sponsors, investigators and the FDA. Who will handle the requests, prepare and distribute responses and monitor the activities to insure that consumers are not misled?

Comment 9: Should the Congress decide to mandate through legislation that DHHS administer a data bank which includes information on device trials, the FDA will require additional funding and resources. Any data bank of public health information for consumers must be maintained and closely monitored for accuracy by the FDA. A lack of agency oversight in this regard will result in a potential for considerable public deception.

The FDA should not simply consider the cost implications for the agency, but rather consider the cost implications for the device industry, IRBs and investigators. Should a data bank be established, mechanisms would need to be developed and instituted for patients and their doctors to obtain information from all sources.

Comment 10: Although directly dependent on how "serious and life-threatening" is defined by the FDA, there is the distinct likelihood that consumers will not understand the information posted in a data bank.

With the exception of devices eligible for a humanitarian device exemption (HDE), there are usually alternative therapies to devices undergoing clinical study. In the case of HDEs, there is usually no clinical study to include in a DHHS data bank. This will be

extremely confusing to consumers, but may also reflect on a very low public health need for the data bank

Summary:

Clearly, the American public has the right to know of the existence of clinical trials funded with their tax dollars. Thus, there is a legitimate obligation for the National Institutes for Health to disclose such information. Likewise, public held device companies are obligated to disclose, through the Securities and Exchange Commission, some of their product development activities that have a direct bearing on investors. It is a totally different, and far more serious, matter for the federal government to decide to obligate sponsors of device trials to publicly disclose their activities for a potential benefit to a select few. If the outcome of device trials is of critical public health importance, as I am sure we agree it is, we should leave the completion of the trials to the individuals responsible for their conduct without additional pressures created through federal disclosure.

Thank your for the opportunity to comment on this fascinating and intriguing topic.

Steven Rohr

cc: Robert Gatling, Center for Devices and Radiological Health

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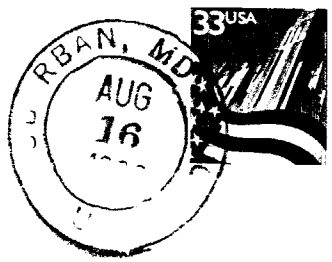

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